

### **REMARKS/ARGUMENTS**

The Applicant's are filing a RCE in response to the Final Office Action mailed December 2, 2003 in addition to a request for one-month extension for response. Claims 1, 9-11, 14 and 15 have been amended. Claims 16-20 have been canceled. New claim 23 has been added.

Claims 1-15 have been rejected under 35 USC 103(a) as being unpatentable over Waite et al (US 5,869,459) in view of John Hopkins Press Release, *Zinc Supplements Important in Combating Diarrhea*, November 27, 2000. The John Hopkins Press release teaches that children suffering from acute and persistent diarrhea benefit from a zinc supplement. The zinc supplement was given in conjunction with oral rehydration therapy. A problem with oral zinc relates to its taste. The unpleasant taste of zinc is well documented in the literature regarding the use of zinc in treating the common cold. While zinc's impact on the common cold may be controversial, the negative metallic taste associated with zinc is not. For example, refer to Marshall's review of the use of zinc in Canadian Family Physician, 44:1037-1042 (1998.) Bad taste was a commonly observed complaint among participants. Further, the professional taste panel utilized in the current application described the taste of zinc solutions to include bitter and musty notes as well as an astringent mouth feel (as described in sample 530 and 442 on Table VII of the instant specification).

Taste is an important factor in the rate of compliance with ORS, especially in children. The concentration of glucose in ORS is too low to mask the salty taste. Many children object to this taste and refuse to consume the ORS, even if the ORS is flavored. At the initiation of the research leading to this invention, the inventors believed that zinc would significantly decrease the palatability of the ORS and further exacerbate compliance issues, especially in a juvenile population.


Waite et al underscore the inventor's belief. Waite et al. addresses the problem of pediatric compliance with ORS therapy. At column 3, line 8, Waite et al states that electrolytes generally have a disagreeable taste. The electrolytes create an unpleasant taste sensation, creating difficulties in getting young children to consume ORS's, despite their diarrhea. Waite et al. discovered that by freezing the ORS, the taste is more acceptable to children.

The disagreeable flavor notes of a solution containing zinc were masked in the John Hopkins study by separately administering the zinc in tablet form. One knowledgeable in the art would not be motivated to add another "nasty" tasting mineral to an already marginally acceptable oral solution, especially since John Hopkins demonstrated that a zinc supplement was successfully administered to this patient population. In accordance with the claimed invention, the Inventors discovered that zinc may be incorporated into a solution without adversely affecting the flavor of the oral solution. In fact, it was often difficult to differentiate zinc-supplemented solution from control solutions in sensory testing (see table VII). The inventors have surprisingly discovered that citric ions blunt the objectionable flavor associated with zinc, even in an unflavored oral solution. The Inventors request that the rejection to the above claims be removed and the claims be allowed as amended.

Claims 16-20 have been rejected under 35 USC 103(a) as being unpatentable over Waite et al (US 5,869,459) in view of John Hopkins Press Release, *Zinc Supplements Important in Combating Diarrhea*, November 27, 2000 and Ndife et al. (US 5,489,440). These claims have been canceled rendering this rejection moot.

Respectfully submitted,

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